Complete Summary

GUIDELINE TITLE

Hyperlipidemia medical nutrition therapy protocol.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Hyperlipidemia medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2001 Jun. Various p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Hyperlipidemia

GUIDELINE CATEGORY

Counseling
Evaluation
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Nutrition

INTENDED USERS

Dietitians

GUIDELINE OBJECTIVE(S)

To provide medical nutrition therapy recommendations for hyperlipidemia that support improvement in lipid levels and risk factor management of cardiovascular disease

TARGET POPULATION

Individuals with hyperlipidemia

INTERVENTIONS AND PRACTICES CONSIDERED

Assessments

1. Medical history and laboratory values including fasting lipid profile (blood cholesterol, low-density and high-density lipoprotein cholesterol, triglycerides), glucose, blood pressure, and others as needed
2. Nutrition-focused assessment including:
    - Height, weight, waist circumference, body mass index
    - Assessment of client´s readiness to learn; comprehensive diet history including current dietary intake (calories, total fat, and sources of fat, cholesterol, sugar, sodium, vitamin E, folate, B-vitamins and alcohol); physical activity pattern; and psychosocial/economic issues impacting nutrition therapy
    - Consideration of comorbid conditions and need for additional modifications in nutrition care plan

Management/Medical Nutrition Therapy

1. Self-management training and materials
2. Individualize nutrition prescription based on National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) guidelines on:
    - Calorie intake
    - Fat and cholesterol intake
    - Trans fatty acid intake
    - Nuts, fish, and soy product intake
    - Soluble fiber intake
    - Plant stanol/sterol products
    - Vitamins/antioxidants intake
3. Meal planning, including food preparation, recipe modification, and dining out
4. Healthful habits, such as limiting alcohol, exercise, smoking cessation
5. Education in potential food-drug interactions
6. Provide self-monitoring strategies
7. Reassessment and follow-up
8. Provide documentation to other relevant health care team members

MAJOR OUTCOMES CONSIDERED

- Serum lipid levels (low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides)
- Risk for and incidence of cardiovascular disease
- Fatal and non-fatal myocardial infarction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The priority for choosing articles to support the American Dietetics Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Hyperlipidemia Protocol were:

1. Randomized control trials to evaluate the effect of various factors (diet, exercise, weight change) on serum lipids (low-density lipoprotein [LDL]-cholesterol, high-density lipoprotein [HDL]-cholesterol, trigylcerides).
2. Cohort studies that evaluated various factors (diet, exercise, weight change) on serum lipids and outcomes (the incidence of fatal and nonfatal coronary heart disease [CHD]). Cohort studies were chosen that had specific inclusion and exclusion criteria, used appropriate methods for evaluating dietary intake or physical fitness and had well-defined outcome measures. Cohort studies were chosen that lasted for ~5 years or more and that collected data upon entry into the study and repeated data collection during the study period.
3. American Heart Association Science Advisory or Nutrition Committee Consensus Statements to identify recent high quality experimental studies (randomized control trials). Review articles that used well-defined criteria for inclusion of studies as part of a meta-analysis or a systematic review and used statistical tests of homogeneity for the meta-analysis studies. Studies chosen provided adequate details of the studies to evaluate the quality of the research.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetics Association Health Services Research Task Force. This process is an adaptation of the US Preventive Task Force evidence analysis process.

Rating Scheme

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion (see the "Rating Scheme for the Strength of the Recommendations" field). Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Plus: indicates that the report clearly addresses issues of inclusion/exclusion, bias, generalization and data collection and analysis

Minus: indicates that the above issues are not adequately addressed

Neutral: indicates that the report is neither exceptionally strong nor exceptionally weak

NA: Indicates that report is not a primary reference and therefore the quality has not been assessed

Classes of Research Reports

A. Primary Reports of New Data Collection

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Decision analysis
- Cost-benefit analysis
- Cost-effectiveness study

Class R:

- Review article
- Consensus statement
- Consensus report

Class X:

- Medical Opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Ideal/Goal Values listed in the American Dietetic Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Hyperlipidemia Protocol is based on a comprehensive review of published peer-reviewed research and literature. In addition, practice guidelines and recommendations supported by national consensus committees, were also used. In instances where guidelines and recommendations vary among consensus panels, the information was carefully analyzed.

Phase I in the development of the hyperlipidemia protocol used the following steps:

Step One: Define the clinical question

Step Two: Conduct a comprehensive search of the literature

Step Three: Gather relevant articles and abstract key information

Step Four: Critique articles and rate the evidence

Step Five: Summarize and integrate results of the review

Step Six: Use the results

The Therapeutic Lifestyle changes in low-density lipoprotein (LDL)-cholesterol Lowering Therapy of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult treatment panel III or ATP III) were followed for topic areas for selecting research reports for review. For example, reduced intakes of saturated fats (<7 %

of total calories) and cholesterol (<200 mg/day), weight reduction and increased physical activity.

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetic Association Health Services Research Tasks Force in December 2000. This process is an adaptation of the United States Preventive Services Task Force evidence analysis process. ICSI process is designed as a practical approach that is user friendly for the clinician. ICSI classifies research reports as:

1. Primary reports of new data collection
2. Reports that synthesize or reflect upon collections of primary reports

Primary reports are categorized according to the level of evidence with category A (randomized, controlled trials) having the highest level of evidence or showing cause and effect. All other primary reports (cohort studies, case studies, nonrandomized trials with concurrent controls) are only able to show an association--not cause and effect. Reports that synthesize or reflect upon collections of primary reports are meta-analysis, systematic reviews, consensus reports, or medical opinion.

Studies and reports were evaluated individually and categorized according to the class of research report and the quality of the research (positive +, neutral, negative -).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A panel of experts, including practitioners and researchers with a depth of experience in the area of practice, convened as the American Dietetics Association (ADA) Medical Nutrition Therapy (MNT) Evidence-Based Nutrition Practice Guideline for Gestational Diabetes Mellitus Writing Group. Their tasks were: first, to agree on a set of recommendations suitable for use in usual clinical situations based on scientific evidence, and where evidence is lacking, on extensive experience and expert opinion; and second, to write the guide (i.e., recommendation) for practice.

Studies and reports within a topic (for example, the effects of restriction of dietary protein on the progression of kidney disease) were given a conclusion grade based on the available evidence. Grade I conclusion is supported by good evidence, Grade II by fair evidence, Grade III by limited evidence and Grade IV only by opinion. The Hyperlipidemia Evidence Analysis Workgroup reached a consensus on the conclusion grade for each topic.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion.

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The American Dietetic Association Medical Nutrition Therapy Evidence-Based Hyperlipidemia Protocol has gone through a comprehensive peer-review process for technical accuracy and content and translation to practice, and meets the criteria for level I (bronze level) validation as defined by the Quality Management Committee of the American Dietetic Association. At the bronze level, recommendations are based primarily on expert opinion and experience. This is a useful starting point when scientific evidence is scarce. By articulating expert

opinion as written guides a defined approach is now available for more consistent implementation and testing.

The Review Panel and Development Committee included experts in the field (experienced dietetics practitioners, specialists, researchers, and educators) and experts and opinion leaders outside the dietetics profession including a medical doctor (MD). The panel utilized a review form to focus feedback on important elements/criteria. In addition, the protocol was evaluated and reviewed for how reasonable expectations are for reimbursement, a critical element for securing medical nutrition therapy coverage in today´s health care market.

Previous versions of this protocol have undergone usability and acceptance level II (silver level) validation and a multi state outcomes project, the Lipid Management Nutrition Outcomes Project (LMNOP), is currently in process. This project is a joint initiative of the Clinical Nutrition Managers (CNM) Dietetic Practice Group of the American Dietetic Association and the Michigan Dietetic Association (MDA). It is occurring in 6 Affiliates (State Dietetic Associations) at a minimum of 5 sites per affiliate and in 2 health care systems. When a guide has been systematically evaluated in routine practice settings and found to meet expectations it qualifies for the silver level. At this level, data from comparative studies provide a fair level of evidence in support of the guide and its recommendations.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Selected recommendations are followed by an evidence grade (I-IV). Definitions for the evidence grades are provided at the end of the "Major Recommendations" field.

Encounter/length: #1 for 60 minutes (Grade: II)

Assessment

A. Clinical data. Obtain from client medical record/information system within 30 days of encounter. To identify the three categories of risk for different low-density lipoprotein cholesterol (LDL-C) goals use Framingham Point Scores-Adult Treatment Panel (ATP) III risk calculator.
    1. Estimate of 10 year risk factors: age, total cholesterol, high-density lipoprotein (HDL) cholesterol, systolic blood pressure, treatment for hypertension, and cigarette smoking.
    2. Review relevant tests, lab values and clinical signs and symptoms.
    3. Review physician´s or other health care team member´s goals for client.
    4. Review medical history and comorbidities, including: hyperlipidemia with coronary heart disease (CHD), cardiovascular disease, cerebrovascular disease, diabetes, hypertension, renal disease, thyroid disease, surgical history, obesity, metabolic syndrome.
    5. Assess prescribed medications that affect nutrition therapy e.g., lipid lowering, antihypertensive, for diabetes (e.g., insulin, antidiabetic), or with potential for food/drug interaction.

6. Obtain medical clearance and assessment for physical activity program.

B. Nutrition-focused initial assessment and comprehensive diet history. Interview client.
    1. Measure or obtain anthropometric data: current height, weight, usual weight, and % weight change, calculate body mass index (BMI), waist circumference. (Grade: II)
    2. Assess knowledge and readiness to learn and make changes with eating behaviors and meal planning to reduce risk factors associated with CHD, other diseases.
    3. Obtain comprehensive diet history including dietary intake data: usual food intake pattern, calculation or estimation of fat intake, percent of calories from fat and type, sources of fat, total fiber intake, soluble-fiber intake. Determine consumption (frequency) of fruits, vegetables, whole grains, legumes, especially foods providing sources of folate, B-6, B-12, vitamin E, and phytochemicals and antioxidants (e.g., berries, deep orange or green fruits and vegetables). Assess intake of fish and soy products and use of plant stanol/sterol esters (e.g., cholesterol-lowering margarine). Review weight history, frequency and choices of restaurant meals, and alcohol intake (frequency, type and amount).
    4. Assess use of dietary supplements (including vitamin, mineral, herbal/botanical (e.g., vitamin E, other antioxidants, garlic, ginger) and over-the-counter (OTC) medications.
    5. Assess physical activity pattern: type of physical activity, frequency, duration, tolerance, and motivation.
    6. Determine psychosocial and economic issues: living situation, cooking facilities, finances, educational background, literacy, employment, ethnic or religious belief considerations, family support, food assistance (if applicable).
    7. Evaluate smoking history (if applicable): present pattern, cessation or participation in smoking cessation program.

Intervention

A. Self-management training. Facilitate self-management training with client on identified goals/nutrition prescription.
    1. Discuss risk factors associated with heart disease.
    2. Explain role and effect of diet, physical activity, weight loss (if applicable), and smoking cessation (if applicable) on CHD and in lipid management.
    3. Provide nutrition prescription based on National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) guidelines. Nutrition prescription should be individualized and based on client needs and priority diet modifications, those modifications not addressed in the initial encounter can be addressed as part of on-going follow-up encounters.
        - Calories based on individual needs, initiate plan to achieve reasonable weight
        - Fats: To initiate the Therapeutic Lifestyle Change (TLC) diet, intakes of saturated fats and cholesterol are reduced first. The range of 25-35% of total calories from fat is to be paired with

keeping saturated fats and trans fatty acid percents of total kcals low.
    - Advise 10% monounsaturated fat, <7% saturated fat, < 200 mg cholesterol diet (Grade: I)
    - If triglycerides >150 mg/dL, ensure blood glucose is under control; limit alcohol and simple sugars, and evaluate need for weight loss. Emphasis should be placed on weight reduction and physical activity
    - Limit foods with trans fatty acids (Grade: II) e.g., stick margarine, shortening, baked products)
    - Select > 5-6 servings/day fruits and vegetables, 6 servings/day whole-grain products
    - Gradually increase total dietary fiber to 20-30 g/day of which 10-25g/day should be (viscous) soluble fiber. (Grade: II)
    - Ensure diet adequate in folate, approximately 400 mcg/day and B-6, 1.3 mg/dL/day. (Grade: II) Consider fortified foods as appropriate.
    - Ensure diet adequate in vitamin E, minimum dietary reference intake (DRI) (12 IU women, 15 IU men) from food sources eg, olive oil, wheat germ, nuts, and seeds. (Grade: II)
    - Select fatty fish (average of 7oz/week) (Grade: II), nuts (1 ounce ~5 times/week (Grade: I) and soy (25g/day) products (Grade: II)
    - Alcohol: limit 1 drink per day (women); 1-2 drinks per day (men). If hypertensive limit to occasional use. Suggest consume alcohol beverages with food. Consider weight status and calorie goals. (Grade: III)
4. Evaluate comorbidities (e.g., hypertension, diabetes mellitus) and need for additional dietary modifications and combination of protocols.
5. Provide an explanation and definitions of fat, types and sources of fat, preferred fats to consume, e.g., methods to reduce saturated fats, increasing monounsaturated fat sources.
6. Discuss food sources that provide beneficial nutrients, e.g., consumption of fruits, vegetables, certain nuts, soy foods, and fish, dairy products or calcium fortified foods.
7. Provide information on fat-free products, consider calorie goals and triglyceride levels and the need to limit fat-free food sources as indicated by lipid levels or weight loss goals.
8. Share techniques for label reading, fat-modified cooking and food preparation methods.
9. Discuss benefits of physical activity, both aerobic and resistance activities, and impact on HDL-C and lipid management. (Grade: II)
10. Discuss self-monitoring techniques useful in recording food and beverage intake, behavior, and physical activity patterns.
11. Establish mutual goals: target laboratory values, weight (maintain or decrease), BMI, waist circumference, blood pressure (if applicable), eating behaviors, food intake and physical activity.

B. Provide self-management training and materials.
1. Review education materials containing information on (customized to client needs):
    - Nutrition prescription, e.g., <7% saturated fat, < 200 mg cholesterol, and meal plan
    - Definition of fats, types of fat with preferred food sources

- Food sources containing trans fatty acids
- Nutrient sources (e.g., foods high in folate, vitamin E, monounsaturated fats, calcium, and soy protein)
- Fiber sources (soluble and insoluble)
- Fat modified cooking and food preparation methods, product information, recipes
- ATP III states considering adding plant stanols/sterols (Grade: II) self management training and materials during the second visit. This allows for establishing the focus on reduction in saturated fat and cholesterol as the primary emphasis
- Alcohol: content and equivalencies of alcoholic beverages
- Self-monitoring records e.g., food/physical activity and behavior records to be kept
- Benefits of physical activity
- Food/drug interaction, if applicable
- Smoking cessation, if applicable

C. Outcome Measurements. Review with client:
- Weight
- Waist circumference
- Blood pressure (if hypertensive)
- Laboratory values (as needed)
- Self-monitoring records (e.g., food, physical activity and behavior records)
- Individualized goals set with the registered dietitian
- Medication (type, frequency, dosage)
- Need for lipid lowering medication, angioplasty or other vascular surgery

Plans for Reassessment and Follow-up

A. Basis. Provide reassessment and follow-up to evaluate response to nutrition therapy.
   1. Schedule appointment in 3-4 weeks.

B. Response to nutrition therapy. Determine based on expected outcomes:
- Maintains or achieves reasonable body weight
- Maintains or decreases waist circumference
- Decreases blood pressure, if applicable
- Decreases blood lipid levels (LDL-C goal levels determined by risk factors [See the ATP III Risk assessment tool for estimating 10-year risk of developing hard CHD (myocardial infarction and coronary death) available from the National Heart, Lung, and Blood Institute (NHLBI) Web site: Online version, Downloadable version]
- Completes self-monitoring records
- Evaluation of food records shows modified intake of fat sources and cholesterol
- Meets goal(s) set with registered dietitian, e.g., reduces the amount of fat and changes sources of fat used in cooking, increases intake of fruits, vegetables, legumes, whole-grain products.
- Increases aerobic physical activities (e.g., increases walking to 15 minutes/day)
- Verbalizes potential food/drug interaction
- Decreases/eliminates need for medication

- Decreases/eliminates smoking (if applicable)
- Prevents/delays angioplasty or other vascular surgery

Communication/Coordination of Care

A. Documentation. Document Initial Assessment and Nutrition Progress Notes in client´s medical record/information system according to organization´s policy.
B. Contact information. Instruct client to call with questions and concerns.
C. Referral source: Send copy of Initial Assessment and Nutrition Progress Notes to physician and place original in client´s medical record.
D. Confirm appointment. Call client 24-48 hours (or send reminder 1 week) prior to next appointment to confirm.

Encounter/length: #2 for 30 minutes

Assessment

A. Clinical data collected. Review client medical record and/or obtain from client interview.
    - Lab values (if available)
    - Blood pressure (if applicable)
    - Current weight, waist circumference
    - Self-monitoring records, e.g., food, physical activity and behavior records kept by client
    - Current medication
B. Outcome Measurements: Review change in client´s
    - Weight, waist circumference
    - Physical activity
    - Intake of total calories, fat, percent calories from fat, sources of fat, trans fatty acids, cholesterol, fiber intake, other beneficial nutrients, e.g., folate, vitamin E
    - Medication(s)

Intervention

A. Nutrition-focused reassessment and brief diet history. Adjust goals and nutrition prescription.
    1. Determine weight change (loss, maintenance), changes in waist circumference, medications, and adjust nutrition prescription, meal plan and goals as needed.
    2. Review self-monitoring records with client, obtain brief diet history, and evaluate client´s adherence to and understanding of the nutrition prescription. Provide feedback on:
        - Percent fat intake and sources of fats, and cholesterol consumed and used in cooking
        - Intake of fruits, vegetables, whole-grain products
        - Fiber intake (soluble sources)
        - Consumption of food sources providing beneficial nutrients (e.g., folate, B-6, vitamin E, soy protein, plan stanol/sterol esters), others as needed
        - Alcohol consumption (if applicable)

- Food and beverage choices and portions to meet calorie and fat goals
- Physical activity (type, frequency, duration and intensity)
- Smoking: packs per day (if applicable)

B. Provide follow-up self-management training and materials.
   1. Provide reinforcement for changes in client´s weight, blood pressure (if applicable), food intake, physical activity, and medications.
   2. Provide rationale for changes in nutrition prescription, meal plan and physical activity to achieve lipid management goals.
   3. Discuss options for achieving nutrient goals, e.g., decreasing saturated fat, adequate calories, calcium, folate, B-vitamins, and vitamin E.
   4. Discuss use of plant stanol/sterol esters (e.g., cholesterol-lowering margarine). (Grade: II)
   5. Discuss fiber sources (soluble and insoluble)
   6. Reinforce self-monitoring techniques, e.g., food, physical activity and behavior records to be kept.
   7. Review education materials containing information on:
      - Food labeling and grocery shopping, product information
      - Fat modified cooking and food preparation methods, product information, recipe modification
      - Food sources containing antioxidants and phytochemicals (e.g., broccoli, tomatoes, leafy green vegetables, fruits)
      - Other food sources (e.g., soy protein, fish providing omega-3-fatty acids, nuts)
      - Fat substitutes and fat-modified foods and appropriate use
      - Information on cholesterol-lowering margarine(s) (if applicable)
      - Simple sugars (if applicable)
      - Supplementation (if applicable)
      - If medication changes, potential food/drug interaction

C. Outcome Measures. Review with client.
   - Weight change (decrease, increase) or maintenance, as appropriate
   - Waist circumference
   - Physical activity
   - Laboratory values (if applicable)
   - Self-monitoring records
   - Individualized goals set with the registered dietitian
   - Medications (type, frequency, dosage)

Plan for Reassessment and Follow-up

A. Basis. Provide reassessment and follow-up to evaluate response to nutrition therapy.
   1. Schedule appointment in 3-4 weeks.

B. Response to nutrition therapy. Determine based on expected outcomes:
   - Maintains or achieves reasonable body weight
   - Decreases waist circumference
   - Decreases blood pressure, if applicable
   - Decreases total cholesterol, LDL-C, triglycerides, glucose, increases HDL-C
   - Completes self-monitoring records
   - Evaluation of food records shows decreased intake of total fat, saturated fat, and cholesterol or modifies food sources containing fat

- Meets goal(s) set with registered dietitian, e.g., reduces the amount of fat and changes type of fat used in cooking, increase intake of monounsaturated fats, limits intake of saturated fats and trans fatty acids, increases intake of fruits, vegetables, legumes, whole-grain products, and limits intake of simple sugars and alcohol (if applicable)
- Increases aerobic physical activities (e.g., increases walking to 15 minutes/day)
- Verbalizes potential food/drug interaction
- Decreases/eliminates need for medication
- Decreases/eliminates smoking (if applicable)
- Prevents/delays angioplasty or other vascular surgery

Communication/Coordination of Care

A. Documentation. Document Nutrition Progress Notes in client´s medical record/information system according to organization´s policy.
B. Contact information. Instruct client to call with questions and concerns.
C. Referral source: Send copy of Nutrition Progress Notes to physician and place original in client´s medical record.
D. Request for clinical data. Request follow-up laboratory values.
E. Confirm appointment. Call client 24-48 hours (or send reminder 1 week) prior to next appointment to confirm.

Encounter/length: #3 and 4 for 30 minutes

Assessment

A. Clinical data collected. Review client medical record and/or obtain from client interview.
    - Current weight, waist circumference
    - Blood pressure reading
    - Laboratory values: fasting cholesterol, triglycerides, LDL-C, HDL-C, fasting glucose, others as needed
    - Self-monitoring records kept by client
    - Medication(s) (amount, frequency and dose)
B. Outcome Measurements: change in client´s
    - Weight
    - Waist circumference
    - Blood pressure
    - Lipid profile (laboratory values), fasting glucose
    - Food/beverage intake, e.g., total calories, fat, percent calories from fat, fiber intake, intake of beneficial nutrients, e.g., folate, vitamin E, others
    - Physical activity
    - Medication(s)

Intervention

A. Nutrition focused reassessment and brief diet history. Adjust goals and nutrition prescription.
    1. Determine changes in weight, waist circumference, BMI, blood pressure, laboratory values (e.g., lipid profile, triglycerides),

medications, and adjust nutrition prescription, meal plan and goals as needed.

- Initiate nutrition prescription for metabolic syndrome as indicated by three or more of the risk determinates: Abdominal adiposity (waist circumference < 40" [102 cm] males, < 35" [88 cm] females), triglycerides (≥150 mg/dL), HDL-C (<40 males, < 50 females); blood pressure (≥130/≥85mmHg); fasting glucose (≥110 mg/dL).
- Intensify weight management
- Increase physical activity
- If hypertension consider: Dietary Approaches to Stop Hypertension (DASH) Diet (Grade: I)
- If triglycerides >500mg/dl then very low fat diet 15% of calories from fat

2. Review self-monitoring records with client, obtain brief diet history, and evaluate client´s adherence and understanding to the nutrition prescription. Provide feedback on:
    - Percent fat intake and sources of fats, and cholesterol consumed and used in cooking
    - Intake of fruits, vegetables, whole-grain products
    - Fiber intake (including soluble sources)
    - Consumption of food sources providing beneficial nutrients (e.g., folate, B-6, vitamin E, calcium, plant stanol/sterol esters)
    - Alcohol consumption (if applicable)
    - Smoking: packs per day (if applicable)

B. Provide follow-up self-management training and materials.

1. Provide reinforcement for changes in client´s weight, blood pressure (if applicable), laboratory values, food intake, physical activity, and medications.
2. Provide rationale for changes in nutrition prescription, meal plan and physical activity to achieve lipid management goals and reduce risk factors.
3. Review previous material or address questions according to client request.
4. Discuss options for achieving key nutrient goals, e.g., vitamin E, folate, calcium, use of cholesterol-lowering margarine(s).
5. Reinforce need for self-monitoring.
6. Review education materials containing information on:
    - Dining out
    - Food sources containing phytochemicals, antioxidants, soy protein, others as individualized to client needs or interests
    - Supplementation (if applicable)
    - If medication changes, potential food/drug interaction

C. Outcome Measures. Review with client.

- Weight change (decrease, increase) or maintenance, as appropriate
- Waist circumference
- Blood pressure
- Laboratory values (if available)
- Self-monitoring records
- Individualized goals set with the registered dietitian
- Medications (type, frequency, dosage)

Plan for Reassessment and Follow up

A. Basis. Provide reassessment and follow-up to evaluate response to nutrition therapy.
    1. Schedule appointment with physician and schedule recheck of lipids in 3 months.
    2. If overweight, continue with weight reduction regimen per organization´s protocol (or refer to Weight Management Medical Nutrition Therapy Protocol).
B. Response to nutrition therapy. Determine based on expected outcomes:
    - Maintains or achieves reasonable body weight
    - Decreases waist circumference, if applicable
    - Decreases blood pressure, if applicable
    - Decreases total cholesterol, LDL-C, triglycerides, glucose, increases HDL-C
    - Completes self-monitoring records
    - Evaluation of food records shows decreased intake of total fat, saturated fat, trans fatty acids, and cholesterol
    - Meets goal(s) set with registered dietitian, e.g., reduces the amount of fat and changes sources of fat used in cooking, increase intake of monounsaturated fats, limits intake of saturated fats and trans fatty acids, increases intake of fruits, vegetables, legumes, whole-grain products, and limits intake of simple sugars and alcohol (if applicable)
    - Increases physical activities (e.g., increases walking to 15 minutes/day)
    - Verbalizes potential food/drug interaction
    - Decreases/eliminates need for medication
    - Decreases/eliminates smoking (if applicable)
    - Prevents/delays angioplasty or other vascular surgery

Communication/Coordination of Care

A. Documentation. Document Nutrition Progress Notes in client´s medical record/information system according to organization´s policy.
B. Contact information. Instruct client to call with questions and concerns.
C. Referral source: Send copy of Nutrition Progress Notes to physician and place original in client´s medical record. If lipid management goals not progressing contact physician for reevaluation of medical treatment plan. Request as needed for additional medical nutrition therapy (MNT) encounters to achieve goals.
D. Request for clinical data. Request follow-up laboratory values or recheck of lipid profile in 3 months if client meeting goals.
E. Confirm appointment. Call client 24-48 hours (or send reminder 1 week) prior to next appointment to confirm.

Definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence (conclusion grade) is specifically stated for selected recommendations (see "Major Recommendations").

The guideline contains conclusion statements that are supported by grading worksheets. These worksheets summarize the important studies pertaining to the conclusion. The quality of the evidence supporting key recommendations (i.e., major dietary components for low-density lipoprotein cholesterol reduction, self-management/individualized counseling, hypertension, homocysteine/folate/B-12, trans fatty acids, soy, fiber, stanols/sterol, alcohol, physical activity, fish, nuts, and body mass index) is graded (positive, negative, neutral) for each study. The type of study is also identified.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Scientific evidence strongly supports the effectiveness of medical nutrition therapy as a means to manage dyslipidemia and reduce risk factors associated with cardiovascular disease. Studies indicate that a reduction in total serum cholesterol, low-density lipoprotein (LDL)-cholesterol levels and drug therapy increases with the level of time spent with the registered dietician.

- A diet low in total fat (<25-35%), saturated fat (<7%), and cholesterol lowers serum total and low-density lipoprotein cholesterol 10% and decreases the risk of coronary heart disease (CHD).
- Individualized dietary interventions provided by a registered dietitian result in a reduction of total dietary fat, saturated fat and serum cholesterol. For changes to occur, a minimum of 2 to 4 encounters with a registered dietitian are needed. Studies demonstrate that greater reduction in cardiac risk factors is achieved with more encounters that are provided by a registered dietitian.
- A diet low in fat, cholesterol and sodium and including low-fat dairy products and rich in fruits and vegetables decreases the chances of developing high blood pressure. Studies with different levels of sodium and different amounts of fruits and vegetables have consistently demonstrated a lowering of blood pressure in hypertensive and normotensive individuals.
- One randomized controlled trial is the only experimental study that demonstrated a significant decrease in nonfatal myocardial infarction (MI) after 1 year of vitamin E supplementation (400 to 800 IU/d) in subjects with CHD.
- Studies focusing on the ingestion of diets containing soy protein as compared with control diets (that did not contain soy protein) demonstrated that soy protein is effective in lowering serum total cholesterol, LDL-cholesterol, and triglycerides ~10% in individuals with hyperlipidemia.
- Consuming diets high in fiber decreased risk factors for CHD as well as CHD cases.
- Plant stanol/sterol esters are effective in lowering serum total cholesterol and LDL cholesterol in both healthy adults and in women with CHD. A reduction of up to 10% total cholesterol is observed when 2-3 g of plant stanol/sterol esters are consumed daily.
- No randomized clinical trials have been done to evaluate the effects of alcohol on high-density lipoprotein (HDL) cholesterol or clinical outcomes (cardiovascular disease [CVD] death, myocardial infarction or stroke). Some studies suggest that wine is more beneficial than other alcoholic drinks and that alcohol increases high-density lipoprotein while decreasing platelet aggregation.
- Observational studies show a direct relationship between physical inactivity and mortality from CHD. Exercise may enhance the beneficial effect of other behavioral interventions.
- Consumption of an average of 7 ounces of fatty fish (high in n-3 fatty acids) per week decreases the risk of death from CHD by ~30% to 40%.
- Consumption of 1 ounce of nuts ~5 times per week decreases total and LDL-cholesterol ~10% to 15% and decreases the risk of CHD by ~30% to 50%.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These nutrition practice guidelines are meant to serve as a general framework for handling clients with particular health problems. It may not always be appropriate to use these nutrition practice guidelines to manage clients because individual

circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have co-morbid, socioeconomic, or other complicating conditions. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical, or other.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

This digital media publication is an integral part of the plans for getting the American Dietetics Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Hyperlipidemia Protocol to all dietetics practitioners engaged in, teaching about, or researching coronary heart disease (CHD) as quickly as possible. National implementation workshops at various sites around the country and during the American Dietetics Association Food and Nutrition Conference is also planned. Additionally there are recommended dissemination and adoption strategies for local use of the Hyperlipidemia Protocol.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Hyperlipidemia medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2001 Jun. Various p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jun

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

Hyperlipidemia Evidence Analysis Workgroup

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print and CD-ROM copies: Available from the American Dietetic Association, 120 South Riverside Plaza, Suite 2000, Chicago, IL 60606-6995; Phone: (800) 877-1600, ext. 5000; Web site: www.eatright.org; E-mail: sales@eatright.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 29, 2003. The information was verified by the guideline developer on August 6, 2003.

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